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SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER ALTER MORSCHAUSER, ALYSSA MARGO	
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* CHARMAINE K. HARRIS and JOSEPH J. KLEIN

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Appeal 2009-005351  
Application 10/773,121  
Technology Center 3700

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Before: WILLIAM F. PATE III, STEFAN STAICOVICI, and  
KEN B. BARRETT, *Administrative Patent Judges*.

PATE III, *Administrative Patent Judge*.

DECISION ON APPEAL<sup>1</sup>

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<sup>1</sup> The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

## STATEMENT OF CASE

Appellants appeal under 35 U.S.C. § 134 from a rejection of claims 1-5, 7-40 and 42-50. App. Br. 3. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

The claims are directed to a percutaneous flat lead introducer. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A stimulation lead introducer comprising:

an elongated dilator defining a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section; and

an elongated sheath defining a sheath lumen sized to accommodate the dilator or a stimulation lead, wherein the sheath comprises a sheath material that is substantially deformable.

## REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Otten	US 5,255,691	Oct. 26, 1993
DeWindt	US 6,146,371	Nov. 14, 2000
Mamo	US 6,847,849 B2	Jan. 25, 2005

## REJECTIONS

Claims 1-5, 7-22, 24-40, and 42-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mamo and DeWindt.<sup>2</sup> Ans. 3.

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<sup>2</sup> The Answer includes claims 6 and 41 in this ground of rejection. However, claims 6 and 41 have been cancelled and are therefore not addressed in this decision. App. Br. 3.

Claim 23 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Mamo, DeWindt, and Otten. Ans. 5.

The provisional statutory double-patenting rejection of claims 1-5, 7-40 and 42-50 is not present in the Answer and has apparently been withdrawn by the Examiner due to the abandonment of the copending application. App. Br. 15.

### OPINION

Appellants first argue that the Examiner erred by finding that since Mamo's dilator, read by the Examiner as including the claimed "sheath," can be constructed from plastic, Mamo thereby discloses a sheath that is "substantially deformable" as required by independent claims 1 and 46. App. Br. 8-10, 13. Appellants repeat this argument regarding claim 49, but claim 49 does not contain this limitation. App. Br. 14. Since plastics, including polyethylenes, can be manufactured to have a variety of stiffnesses, a material is not necessarily "substantially deformable" solely by virtue of being a plastic or polyethylene. *See, e.g.,* Elizabeth Benham & Max McDaniel, Ethylene Polymers, HDPE, Encyclopedia of Polymer Science and Technology (2010), *available at* <http://mrw.interscience.wiley.com/emrw/9780471440260/epst/article/pst408/current/html>. Accordingly, we reverse the Examiner's rejection of independent claims 1 and 46 and dependent claims 2-5, 7-15, 44, 45, 47 and 48.

The next issue raised by Appellants relates to the Examiner's proposed modification of Mamo with the cross-sectional shape taught by DeWindt to teach the claimed "conical distal tip" having a "substantially oblong cross-section". App. Br. 10-14. This limitation is present in claims 1,

16, 38, 46 and 49. The Examiner's findings that Mamo discloses a dilator lacking an oblong cross section and that DeWindt discloses an oval-shaped cannula are not disputed by Appellants. Ans. 4. We adopt these findings as our own. The fact that the Examiner does not rely on a single reference that discloses a dilator having a conical distal tip having an oblong cross section does not establish that the Examiner erred in determining the claimed subject matter would have been obvious under 35 U.S.C. § 103(a). *Contra* App. Br. 10-11. While, as Appellants point out, DeWindt's cannula may be intended for a purpose different from Appellants' and Mamo's, we disagree with Appellants' contention that one of ordinary skill in the art would not have recognized DeWindt's teachings as relevant to Mamo's dilator. App. Br. 11. One of ordinary skill in the art would recognize that minimizing invasiveness to the patient by using the cross sectional shape disclosed by DeWindt would be a predictable advantageous feature of a variety of surgical instruments, including Mamo's dilator. Thus, we find Appellants' argument that the Examiner's proposed combination would have failed to render obvious a dilator tip having a "substantially oblong cross-section" is unpersuasive.

The next issue raised by Appellants is whether the Examiner failed to make a prima facie case of obviousness regarding claim 16 because the Examiner never articulated how the combination of Mamo and DeWindt would have rendered obvious the step of "inserting a stimulation lead introducer to a target site within an epidural region proximate a spine of a patient via a guidewire." Since the Examiner has not mentioned this step in the rejection, nor has the Examiner responded to Appellants' allegation that it is missing from the references, and it is not apparent in Mamo or DeWindt, we agree with Appellants that the Examiner failed to establish a

prima facie case of obviousness regarding claim 16. The key to supporting any prima facie conclusion of obviousness under 35 U.S.C. § 103 is the clear articulation of the reason (or reasons) why the claimed invention would have been obvious. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The Examiner has not carried this burden. Thus, we find that the rejection of claim 16 and dependent claims 17-22 and 24-37 must be reversed. Since, as applied by the Examiner, Otten is not relied upon to cure this deficiency, we are constrained to reverse the rejection of claim 23 also.

The next issue raised by Appellants is whether the Examiner failed to make a prima facie case of obviousness regarding claim 38 because the Examiner never asserted that the combination of Mamo and DeWindt would have rendered obvious a dilator for widening a path for a stimulation lead to travel through an epidural region proximate the spine of a patient. App. Br. 13. This preamble limitation relates to the intended use of the device. Since the claim defines a complete structure without the preamble, the preamble does not breathe life and meaning into the claim and is therefore afforded little patentable weight. Although Mamo does not specify widening a path at the location specified in the preamble, if Mamo's device would be capable of performing the recited intended use, then it meets the claim. Where the limitation relied upon for patentability is functional in nature the burden shifts to Appellants to establish that the prior art relied upon could not perform the claimed function. *In re Swinehart*, 439 F.2d 210, 213 (CCPA 1971). Appellants do not provide any further arguments or factual support for this allegation and have therefore failed to carry this burden. Accordingly, the rejection of claim 38 and dependent claims 39, 40, 42, and 43 is sustained.

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The final issue raised by Appellants is whether the Examiner failed to make a prima facie case of obviousness regarding claim 49 because the Examiner never asserted that the combination of Mamo and DeWindt would have rendered obvious an oblong cross section on the distal end of the stimulation lead. App. Br. 16. Since the Examiner has not addressed this limitation, nor has the Examiner respond to Appellants' arguments, and it is not apparent in the references, we find that the Examiner has failed to articulate a reason why the claimed subject matter would have been obvious. *KSR*, 550 U.S. at 418. Thus, we find that the Examiner's rejection of claim 49 and dependent claim 50 must be reversed.

#### DECISION

For the above reasons, the Examiner's rejection of claims 1-5, 7-37, 44-50 is reversed. The Examiner's rejection of claims 38-40, 42, and 43 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2007).

#### AFFIRMED-IN-PART

nlk

SHUMAKER & SIEFFERT, P. A.  
1625 RADIO DRIVE  
SUITE 300  
WOODBURY MN 55125